REMARKS

The Final Office Action dated May 11, 2009 has been reviewed, and the comments of the U.S. Patent Office have been considered. All withdrawn Claims have been cancelled, to permit focus on Claims previously presented. Thus, Claims 59 – 91 and 95 – 131 have been cancelled, as it appears from the Examiner's statements of acknowledged fact in the outstanding Office Action that the rejection of the pending claims is based solely on a misapplication of law, and that these claims may be allowed without further amendment. Accordingly, Claims 93, 94 and 132 – 134 remain pending, and are not amended herein. Reconsideration is respectfully requested.

Claim Rejections – 35 U.S.C. § 112

The sole outstanding rejection of the pending claims is for lack of enablement. In advancing this rejection, the Examiner does not apply it separately to separate claims, notwithstanding their differences in scope. This appears to be the case because the Examiner has misapplied the law, demanding Applicants disclose, in enabling fashion, not what they claim, but some ultimate embodiment that might be commercially or therapeutically desirable. The rejection of Claims 93, 94 and 132-134 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement is respectfully traversed.

It is respectfully submitted that it is important to observe the limits of the enablement requirement – Applicants for patent are required to enable **that which they claim** not that which someone else might achieve with their invention. In particular, the level of disclosure varies

according to the specific limitations of the claims – what do the claims require. *Durel Corp v. Osram Sylvania, Inc.,* 256 F.3d 1298, 1306-07 (Fed. Cir. 2001).

Importantly, nothing in the claims requires that the inventive method result in therapeutic treatment of AIDS in a human or mammal. Importantly, nothing in the claims requires that the peptide recited exhibit a particular "binding specificity, selectivity and affinity, oral bioavilability, cellular uptake, toxicity, lethal dose, and side effects for administering a PTAP-containing peptide into a cell inside a body." See, Office Action, page 11. Importantly – *nothing in the claims requires the method claimed to have any therapeutic activity at all*. It would be wonderful if it did – and Applicants continue to believe it might, if developed properly – but THAT is NOT Applicants' invention.

The claims – in their very broadest rendition, require only that a peptide be administered to cells infected with HIV. There is nothing difficult about that – this has been done for years and the specification is replete with examples of this. The claims, in their very broadest rendition, further require that the administered peptide comprise a PTAP motif. There is nothing difficult or not enabled about this….those of skill in the art know HOW to prepare peptides with a PTAP sequence or motif, and even if they did not, the specification contains examples of the same, including SEQ ID Nos. 3 and 4. This is clearly enabled.

The claims, in their broadest rendition, further require that the PTAP comprising peptide be administered to the cells in an amount which inhibits binding between tumor susceptibility gene protein (TSG101) and HIV Gag polypeptide. And this of course is what the case is all about, the very long specification demonstrating by specific example, including assays and

results, that peptides of the type recited do indeed inhibit binding between TSG101 protein and HIV Gag polypeptide. Because this binding event is a prerequisite for HIV particle generation, the administration of these particles inhibits that generation. Here is what the Examiner and the Office had to say about whether the specification enables one of skill in the art to identify these PTAP comprising peptides that interfere with binding between TSG101 and HIV Gag protein:

> The instant specification discloses…an assay for identifying all PTAP-containing peptides that are effective at inhibiting the binding between Tsg101 and the HIV Gag protein and thereby blocking the HIV particle generation step in the virus lift cycle.

See, Office Action of November 25, 2008 at page 8 and Office Action of May 11, 2009, page 10. Applicants agree with the Examiner that the specification does in fact enable one to find the class of peptides recited in the claims!!!

Thus, Applicants respectfully submit that all aspects of the **claimed** invention are enabled. One can see this as follows:

Claim 93 recitations	**Record Evidence**
Administering to cells suspected of being infected with HIV an amount of a compound	This has been done for years, but the specification specifically teaches administration of this compound, and amounts to be administered. Pages 17 – 18, pages 31, 34, 41.
The compound is a peptide comprising a PTAP motif	Even a freshman chemistry student can construct and recognize a peptide which comprises a PTAP motif. But examples are given in SEQ ID Nos 3 and 4
The peptide comprising the PTAP motif inhibits binding between TSG101 protein and HIV Gag polypeptide and thereby inhibits HIV	The instant specification discloses…an assay for identifying all PTAP-containing peptides that are effective at inhibiting the binding between Tsg101

particle generation	and the HIV Gag protein and thereby blocking the HIV particle generation step in the virus lift cycle. Office Actions of November 25, 2008 and May 11, 2009.

So what aspect of the Claims is not enabled? As discussed below, Applicants submit that which the Examiner finds to be not enabled is therapeutic treatment of humans exhibiting AIDS – certainly a laudable goal, but not what Applicants claim in this case.

Before turning to the Examiner's arguments, Applicants again respectfully request reconsideration of the impact of U.S. Patent 7,494,767. That patent claims, *inter alia,* methods for identifying a peptide which comprises a PTAP motif, where that peptide is effective in reducing HIV particle production. That patent, with a disclosure IDENTICAL to that of the above application, is presumed enabling. *Amgen Inc. v. Hoechst Marion Roussel* Inc., 65 USPQ2d 1385, 1416 (Fed. Cir. 2003), *Sanofi-Synthelabo v. Apotex Inc.,* 89 USPQ2d 1370, 1376 (Fed. Cir. 2008). As previously noted by Applicants, if the same disclosure is enabling for the method of making and using these peptides, then the necessary conclusion is that the pending disclosure must be as well.

The Examiner does not disagree, but says only:

> U.S. Patent 7,494,767 is not germane to the rejection at issue because each case is evaluated on its own merits. Office Action of May 11, 2009, p. 12.

Respectfully, the Examiner is wrong. The case law of the Federal Circuit establishes that the disclosure provided in the above application is presumed to be enabling for the peptides in

question, independent of its "own merits." Should the Examiner elect to persist in the rejection, the Examiner is specifically invited to comment on how it can be that the '767 patent is presumed enabling for the peptides recited in the claims, but the current case is not. Simply saying it is different is not responsive. The enablement issue is the same.

Applicants Need Not Enable a Cure for AIDS

The Office Action does not seriously question whether one of skill in the art, given the identification of peptides that interfere with TSG101 – HIV Gag binding and thereby inhibit HIV particle production, would be able to administer them to a cell infected with AIDS. Indeed, examples of how to do this are provided. Rather, the Examiner questions whether the peptides, so administered, will be effective in treating AIDS. Quite simply, this is something the Federal Circuit has held Applicants need not do.

Applicants return to the observation that what needs to be enabled is determined ONLY by the limitation of the claims.

> "The ' enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.' " *Sitrick v. Dreamworks, LLC,* 516 F.3d 993, 999 (Fed.Cir.2008) (quoting *AK Steel Corp. v. Sollac,* 344 F.3d 1234, 1238-39 (Fed.Cir.2003)). (Emphasis supplied).

Because Applicants recognize that there may be situations where what the Examiner refers to as "pharmacokinetic problems" (Office Action, page 6) might prevent the administration of a peptide that inhibits binding between TSG101 and HIV Gag and thereby inhibits virus particle generation from effectively treating AIDS in a human or animal, and Applicants have not had an opportunity to present data with respect thereto, Applicants have not claimed treating or inhibiting AIDS or HIV in any manner of beast.

While this is the ultimate possibility of the enabled claims, it is NOT what Applicants claim. The Federal Circuit has previously rejected the type of analysis employed by the Examiner here. In *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F. 3d 1333, 1338 – 39, the Federal Circuit noted that, absent a claim limitation drawn to such an embodiment, one need not enable it.

Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect. Title 35 requires only that the inventor enable one of skill in the art to make and use the full scope of the claimed invention. Thus, when an invention claims a general system to improve the cleaning process for semiconductor wafers, the disclosure enables that invention by showing improvements in the overall system. *See, e.g.,* Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed.Cir.1991)

When Applicants claim a method for treating AIDS *in vivo*, they should be put to the standard applied by the Examiner herein. They have not claimed such an invention herein.

Thus, at page 5, the Examiner argues there is no shown correlation between the results provided and "*in vivo* efficacy" in part because "there is no teaching about the therapeutic properties…for administering a PTAP-containing peptide into a cell inside a body." At pages 5 – 6 the Examiner discusses failed attempts to provide an effective treatment for HIV infection, including failure to understand molecular determinants, failure of adequate predictions of clinical efficacy, failure to achieve acceptable pharmacological profiles and failure of structural analogs to function in the desired manner. Applicants' claims do not embrace "structural analogs" of anything – the identification of the agent administered, the peptide, and its use to inhibit particle formation, the PTO has agreed is enabled. The remaining concerns, including those obstacles to "developing efficacious anti-HIV agents (Office Action page 6) do not address

the invention claimed here. Respectfully, the Examiner reveals the error in the application of 35 USC § 112 where it is stated:

> In the instant case, a Tsg101-Gag binding inhibitor as an AIDS drug is not considered routine in the art. (emphasis supplied). Office Action, page 7.

That is not the 'instant case." Applicants' claims do not recite anything about an AIDS drug. Repeatedly, the Examiner notes that the claims embrace methods whereby effective inhibition in a human body might in fact treat AIDS. Maybe so – certainly mankind should hope so. But that is not Applicants' claim. With regard to the methods of administering the compound, Applicants note that the Federal Circuit has repeatedly held that "the enablement requirement is met if the description enables any mode of making and using the claimed invention." *CFMT*, supra, quoting *Engel*, supra. The Examiner concedes that at least one method of administering the compounds recited is in fact enabled. Even if the Examiner is correct that a method of administering it therapeutically (not recited) to treat or cure AIDS (not recited) is not enabled by the pending disclosure – it has no bearing on the claims presented.

Applicants' claims are narrowly drawn. Indeed, Claim 132 is confined to administration of a specific peptide fully enabled by the specification. It is not clear how failure to show this enabled method effectively cures AIDS can somehow stand as a basis for lack of enablement. Should the Examiner elect to maintain the rejection, Applicants' specifically request the Examiner indicate the arguments offered in support of the rejection of Claim 132.

CONCLUSION

In view of the foregoing evidence and remarks, Applicants respectfully request reconsideration of this Application and the prompt allowance of at least Claims 93, 94 and 132-134.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0548.

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Respectfully submitted,

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